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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,593	11/14/2003	Hua Xu	056274-3451	3233

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,593	XU ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-30* is/are pending in the application.

4a) Of the above claim(s) *17 and 24-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-16 and 18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to the Amendment

The Amendment filed on 2/20/2007 in response to the previous Non-Final Office Action (8/18/2007) is acknowledged and has been entered.

Claims 1-2 and 4-30 are currently pending.

Claims 17 and 24-30 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1-2, 4-16 and 18-23 are currently under consideration.

Rejection Withdrawn:

The rejection of claims 1-2, 10-16, 18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicants amendments.

Rejections Maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-16 and 18-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kauvar et al. (US 5,955,432, 1999) (*referred to herein as Kauvar '432*) in view of Kauvar et al. (US 5,556,942, 1996, IDS) (referred to herein as Kauvar '942) as evidenced by USP Dictionary of USAN and International Drug Names (2005, of record).

Kauvar '432 teaches a method of protecting a subject from the destructive effects of a chemotherapeutic agent, including irradiation, comprising administering to a subject an effective dose of a glutathione analog (column 2, lines 48-55). With regards to the destructive effect, the patent teaches that the glutathione analogs mitigate the bone-marrow destructive effects of chemotherapeutic agents (abstract). With regards to the subjects, the patent teaches that the subjects include, but are not limited to, vertebrate subjects, particularly mammalian or human subjects (column 7, lines 20-23). With regards to the dose, the patent teaches that the dosage required depends of the nature of the subject, the nature of the condition, the manner of administration and the judgment of the attending physician, but will be in the range of 0.1-100 mg/kg per day for 10 to 40 days (column 7, lines 47-55). With regards to the administration of the glutathione analog, the patent teaches that the timing of administration of the glutathione analog with respect to the chemotherapeutic agent depends on the nature of the chemotherapeutic agent used (column 7, lines 56-59). For example, the patent teaches that when 5-FU is used for chemotherapy, administration seems advantageous about 24 hours subsequent to administration of the 5-FU, whereas administration of the glutathione analog about 24 hours prior to cisplatin treatment is effective (column 7, lines 60-65). Moreover, the patent teaches a method of treating tumors comprising administering a glutathione analog in combination with Melphalan, wherein the glutathione analog potentiated the inhibitory effect of Melphalan (column 10, *Example 2*).

Kauvar et al. do not explicitly teach that the glutathione analog is a GST-activated anticancer compound.

Kauvar '942 teaches (column 5, lines 36-41) a method of treating tumor cells comprising administering glutathione S-transferase-activated compounds (GST), wherein the glutathione-S transferase activated compound are selectively cleaved by the tumor cells to release a cytotoxic agent. With regards the GST-activated anticancer compounds, the patent provides (column 4, lines

22-26 and beginning with column 5, line 1 to column 8, line 53) compounds which appear to be 100% identical to the presently claimed GST-activated anticancer compounds, wherein the GST-activated compounds comprise a glutathione (GSH) coupled to a leaving group such as a phosphoramide mustard, phosphorodiamidate mustard, a chemotherapeutic agent, toxin, anti-inflammatory or steroid based drugs. In one embodiement, Kauvar '942 disclose a method of treating a tumor comprising administering 300 mg/kg of a GST activated anticancer compound referred to as TER 286 (column 20, lines 21-33). Moreover, the patent teaches (column 4, lines 37-40) that the GST-activated compounds of the invention are useful for the treatment of drug resistance in cancer cells. Furthermore, Kauvar '942 disclose (column 5, lines 42-49) that the GST-activated compounds provide a chemotherapeutic agent to a tumor cell while protecting the function of bone marrow. As such, the patent teaches that the glutathione S-tranferase-activated compounds are useful for selective treatment of target tissues, which contain compatible glutathione S-transferase isoenzyme, and simultaneously elevate the levels of GM progenitor cells in bone marrow (abstract). Although Kauvar '942 do not specifically teach that the GST-activated agent referred to as TER286 is the presently claimed canfosfamide, the claimed limitation would be an inherent property of the referenced compound because as evidenced by USP Dictionary of USAN and International Drug Names, canfosfamide hydrochloride is also referred to as TER 286 (page 155 to 156, last compound taught on page 155). Thus, the claimed compound appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the GST-activated compound does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the glutathione derivative taught by Kauvar '432 with a GST-activated anticancer compound as taught by Kauvar '942. One would have been motivated to do so because each of the agents have been individually taught in the prior art as being effective at mitigating the bone-marrow destructive effects of chemotherapeutic agents. In addition, Kauvar

'942 teach that on top of being a bone marrow protectant, the GST-activated anticancer compounds are also useful for selective treatment of target tissues, which contain compatible glutathione S-transferase isoenzyme. Thus, one of ordinary skill in the art would have reasonable expectation of success that by administering a GST-activated anti-cancer compound in combination with a chemotherapeutic agent, one would achieve a method of treating cancer, as well as, a method of mitigating the bone-marrow destructive effects of chemotherapeutics agents such as cisplatin.

Secondly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the chemotherapeutic agents taught by Kauvar '432 with a GST-activated anticancer compound as taught by Kauvar '942 because each of the agents have been individually taught in the prior art to be effective at treating cancer. The instant the instant situation is amenable to the type of analysis set forth in In re Kerkhoven,205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant process claims, one of ordinary skill in the art would have reasonable expectation of success that by administering a GST-activated anti-cancer compound in combination with a chemotherapeutic agent, one would achieve a method of treating cancer, as well as, a method of mitigating the bone-marrow destructive effects of chemotherapeutics agents such as cisplatin.

Furthermore, it would have been prima facie obvious to one or ordinary skill in the art at the time the invention was made to optimize the dosage and interval schedule of canfosfamide hydrochloride. One would have been motivated to do so because as taught by Kauvar '432, the dosages, formulations and administration schedules will vary in cancer patients compared to normal patients. Therefore, where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. As such, one would have a reasonable expectation of success that by optimizing the administration schedule, one would achieve a successful method of treating cancer, as well as, a method of mitigating the bone-marrow destructive effects of chemotherapeutics agents such as cisplatin.

In response to this rejection, Applicants assert that not only does Kauvar '423 "not explicitly teach that the glutathione analog is a GST-activated anticancer compound", the glutathione analogs of Kauvar '432 are not GST-activated anticancer compounds; and further, are not the GST-activated anticancer compounds of the present claims because, although they contain glutathione or a glutathione analog, they do not contain a glutathione or glutathione analog chemically linked to a cytotoxic moiety such that the cytotoxic moiety is released by cleavage from the glutathione or glutathione analog in the presence of one or more GST isoenzymes. Moreover, Applicants submit that they do not dispute that Kauvar '942 discloses the class of GST-activated anticancer agents claimed in amended claims 1-2, 4-16 and 18-22, including TER286. However, Applicants assert that there is not suggestion or motivation to combine the teachings of Kauvar '432 and Kauvar '942 because the glutathione analogs of Kauvar '432 are GST isoenzyme inhibitors, not GST-activated anticancer compounds. Thus, Applicants assert that Kauvar '432 does not provide suggestion or motivation to replace the glutathione analog GST isoenzyme inhibitors with an anticancer agent, still less particular GST-activated anticancer agents of Kauvar'942. Likewise, Applicants assert that Kauvar '942 does not provide any suggestion or motivation to use their GST-activated anticancer agents in combination cancer therapy-they propose that the compounds may be used by themselves. Applicants further assert that the statement in the Office Action regarding the motivation because each have been individually taught in the prior art to be effective at mitigating the bone-marrow destructive effects of chemotherapeutic agent is not to the contrary. In particular, Applicants assert that nothing in Kauvar '942 suggest the use of its GST-activated anticancer compounds in combination cancer therapy or that a GST isozyme inhibitor would be useful in combination cancer therapy (since Kauvar '942 do not disclose GST isoenzyme inhibitors), and equally nothing in Kauvar '492 suggest that a GST-activated anticancer compound would be useful in combination cancer therapy because Kauvar '432 talks about GST isoenzyme inhibitors and not about GST-activated anticancer compounds, and give no reason to substitute a GST-activated anticancer compound for the glutathione analog and therefore, the asserted combination cancer therapy benefit which is based on that GST isoenzyme inhibitory activity. Along these lines, Applicants assert no physician or oncologist would substitute, for example, amlodipine, for, for example captopril, because commonality of effect and substitutability cannot be equated. Furthermore, Applicants contend that while *Kerkhoven* suggest that combining compositions known to be equivalent under the

facts of that case for the same purpose was prima facie obvious, cases such as *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987) teach that there is no presumption of obviousness in combination ("Based upon the prior art and the fact that each of the three component of the composition used in the claimed method is conventionally employed in the art for treating cooling systems, the board held that it would have been prima facie obvious, within in the meaning of 35 U.S.C. 103, to employ these components in combination for their known functions and to optimize the amount of each additive... Appellant argues... hindsight reconstruction or at best,... 'obvious to try'... We agree with appellant." In the instant case, Applicants assert that it is indisputable that one cancer chemotherapeutic agent is not equivalent for another in general; and further, it is indisputable that cancer chemotherapeutic agents are not combinable just for the reason that they are cancer chemotherapeutic agents-they are not for a number of reasons, not least that the toxicities of the two agents, each of which is tolerable alone, may combine to make the combination regimen unacceptably toxic. As such, Applicants assert that there is no suggestion or motivation in the prior art to combine the chemotherapeutic agents taught by Kauvar '432 with a GST-activated anticancer compound as taught by Kauvar '942 "because each of the agents have been individually taught in the prior art to be effective at treating cancer". In other words, Applicants assert that the fact that the chemotherapeutic agents taught in Kauvar '432 as being potentiable by the glutathione analogs of Kauvar '432 are chemotherapeutic agents and the GST-activated anticancer compound of Kauvar '942 is also a chemotherapeutic agent does not provide motivation for the combination in view of the well known difficulties of combination cancer chemotherapy. Thus, Applicants assert that since there is no motivation for the combination, there is no reasonable expectation of success in the proposed combination. Lastly, Applicants assert that they have unexpectedly discovered that a GST-activated anticancer agent as claimed in amended claim 1 and its dependent claims is combinable with another anticancer therapy with beneficial effect and relative lack of increase in toxicity, ant that this is unobvious in view of the cited art.

These arguments have been carefully considered, but are not found persuasive.

First, the Examiner acknowledges and agrees with Applicants assertions that the glutathione analogs of Kauvar '432 are not GST-activated anticancer compounds as claimed in the present claims; and further, that Kauvar '942 discloses the class of GST-activated anticancer agents claimed in amended claims 1-2, 4-16 and 18-22, including TER286. However, with regards to Applicant's

argument that there is no suggestion or motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (Ruiz at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the art (National Steel Car v. Canadian Pacific Railway Ltd., 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed.Cir. 2004)). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969). In the instant case, as taught above, one of skill in the art would recognize that each of the glutathione derivatives have been individually taught in the prior art to be effective at mitigating the bone-marrow destructive effects of chemotherapeutic agents; and further, that in addition to being a bone marrow protectant, the glutathione derivatives taught by Kauvar '942 are also anti-cancer agents useful for selective treatment of target tissues, which contain compatible glutathione S-transferase isoenzyme. As such, the motivation to combine the references lies in the fact that in addition to being a bone marrow protectant similar to the compounds disclosed by Kauvar '432, the glutathione derivatives of Kauvar '942 are also anticancer agents. Similarly, regarding Applicants opinion about substituting one drug for another, the Examiner acknowledges Applicants opinion and agrees with Applicants one example pertaining to the platinum based chemotherapeutics, e.g., substituting cisplatin for oxaliplatin for the treatment of lung cancer. However, the Examiner recognizes that while cisplatin cannot be substituted for oxaliplatin for the treatment of lung cancer, one of skill in the would recognize that cisplatin could be substituted for carboplatin because, as discussed by Applicants, both are used in lung cancer treatment. As such, the Examiner does not share Applicant's opinion with respect commonality of effect and substitutability cannot be equated. In the same way, if one is suffering from a fever or swelling, e.g., inflammation, and just cannot take aspirin, one of skill in the art, including a physician, would recognize that ibuprofen, sold under the brand-names Advil™ and

Nuprin™, is a substitute for aspirin for the treatment of fever and swelling. In the instant case, each of the each of the glutathione derivatives have been individually taught in the prior art to be effective at mitigating the bone-marrow destructive effects of chemotherapeutic agents and therefore, one of ordinary skill in the art would have a reasonable expectation of success that by substituting the glutathione derivatives as taught by Kauvar '432 for the glutathione derivatives as taught by Kauvar '942, one would achieve a method of mitigating the bone-marrow destructive effects of chemotherapeutic agents. Regarding Applicants assertions with respect to the reliance on In re Geiger, the Examiner acknowledges and agrees with the courts decision in Geiger that there is no presumption of obviousness in combination. However, the Examiner recognizes that the fact patterns involved in Geiger are different from those of the instant inventions. For example, the facts involved in Geiger were that while each of the prior art references taught the individual use of the one of the three components in combination with other components in the treatment of a water cooling system, there is no suggestion to add, for example, a zinc compound to the disclosed combination of SSMA and organo-phosphorus acid compounds taught by Snyder '733, or to use SSMA in combination with an organo-phosphorus acid compound in the treatment of a cooling water system, wherein the characteristics may significantly differ from those in Hwa's boiler water system. In the instant case, Cisplatin is an art-recognized and well known chemotherapeutic agent which has been taught in the prior art and by Applicants to be useful for the treatment of cancers such as lung cancer and in view of the teachings of Kauvar '942, glutathione S-tranferase-activated compounds are useful for selective treatment of target tissues, which contain compatible glutathione S-transferase isoenzyme such as lung cancer (see for example, column 2, lines 61-65). Thus, the fact pattern involved in the instant case is more applicable to the type of analysis set forth in Kerkoven wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. In addition, in contrast to Applicants opinions which have not been supported by any scientific reasoning that it is indisputable that cancer chemotherapeutic agents are not combinable just for the reason that they are cancer chemotherapeutic agents-they are not for a number of reasons, those of skill in the art recognize that it is conventional in the art to combine two chemotherapeutic agents, each of which has been taught

to be effective at treating the same tumor. For example, DeVita et al. Cancer. Principles & Practices of Oncology, Lippincott Williams & Wilkins. 6th Edition. 2001. Chapter 17, page 292) teaches that "[C]ombination chemotherapy using conventional cytotoxic agents accomplishes several important objective not possible with single-agent treatment. First, it provides maximal cell kill within the range of toxicity tolerated by the host for each drug as long as the dosing is not compromised. Second, it provides a broader range of interaction between drug and tumor cells with different genetic abnormalities in a heterogenous tumor population. Finally, it may prevent or slow the subsequent development of drug resistance." As such, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the chemotherapeutic agents such as Cisplatin taught by Kauvar '432 with a GST-activated anticancer compound as taught by Kauvar '942 because each of the agents have been individually taught in the prior art to be effective at treating lung cancer. Lastly, regarding Applicants assertion with respect to an unexpected discovery, the Examiner recognizes that the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicants. As such, Applicants arguments with respect to an unexpected discovery are moot.

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

Therefore, NO claim is allowed

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the

THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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